UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency Office of Pesticide Programs

MEMORANDUM

9/6/2018

SUBJECT: Product Chemistry Review for **2015,** EPA Reg. No.: **92082-R**

FROM: Vekalet Tek, Ph.D.
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

THRU: Karen P. Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)
9/19/2018

TO: Eric Miederhoff, PM Team 31 / Karen Leavy
Regulatory Management Branch I
Antimicrobials Division (7510P)

Registrant: Allied Bioscience Inc.
Action code: A540
Agency Due Date: 10/15/2018
DP No.: 446966
Submission No.: 1018991
E-Sub No:28671
Classification: EP
Process: Nonintegrated system
Pesticide type: Microbiostat

MRID(s): 50576301, 50576302, 50576304, 50576311, 50576312

Formulation from label			
PC code(s)	CAS #(s)	Active Ingredient(s)	% weight
107401	27668-52-6	3-(trihydroxysilyl)propyldimethyloctadecyl ammonium chloride	0.75%
		Other Ingredients	99.25%
		Total	100.00%

I. BACKGROUND

The Registrant, Allied Bioscience Inc., has submitted a pesticide registration for their product: 2015, EPA Reg. No. 92082-R and requested a review of the proposed Basic CSF, Group A and Group B data.

II. RELEVANT DOCUMENTS

	RECEIVED	N/A
EPA FORM 8570-27 – Formulator's Exemption Statement	☒	☐
EPA FORM 8570-35 – Data Matrix (4/23/2018)	☒	☐
Cover letter (4/23/2018)	☒	☐
Transmittal document	☒	☐
Proposed CSF BASIC, (4/23/2018)	☒	☐
Proposed label (4/20/2018)	☒	☐
Certification for Pilot Fragrance Notification Program	☐	☒
	☐	☐
REFERENCED: CSF	--	
Comments: None.		

III. FINDINGS

a. Product Formulation:

	TGAI	MUP	EUP	Food use	Non-food use
Non-integrated	☐	☐	☒	☐	☒
Integrated	☐	☐	☐		

Active Ingredients(s)	Nominal	Upper limit	Lower limit
3-(trihydroxysilyl)propyldimethyloctadecyl ammonium chloride	0.750%	0.825%	0.675%
	YES	**NO**	**N/A**

1. The certified limits of all ingredients are within 40 CFR standard certified limits.	☒	☐	☐
2. Wider certified limits were requested and rationale was accepted.	☐	☐	☒
3. The nominal concentration(s) of the active ingredient is in agreement with the label.	☒	☐	☐
4. The chemical IDs and analytical information for density, pH, and flammability are consistent with Series 830 Group B data.	☒	☐	☐
5. All inert ingredients are approved for non-food use pesticide formulations.	☒	☐	☐
6. The impurities present >0.1% are identified.	☐	☐	☒
7. Impurities of toxicological significance have an upper certified limit.	☐	☐	☒

b. Product Label:

	Yes	NO	N/A
The formula contains one of the following:			
1. 10% or more of petroleum distillate	☐	☒	☐
2. 1.0% or more of methyl alcohol	☐	☒	☐
3. Sodium nitrite at any level	☐	☒	☐
4. A toxic list 1 inert at any level	☐	☒	☐
5. Arsenic in any form	☐	☒	☐
6. If yes to 1-5, then the inert ingredient list contains a relevant footnote	☐	☐	☒
7. Appropriate warning statements regarding flammability or explosive characteristics of the product are included on the label	☐	☐	☒
8. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.	☒	☐	☐
9. The product requires an expiration date at which time the nominal concentration falls below the lower certified limit (**Initial % by weight concentration of the active ingredient is below the lower certified limit**).	☒	☐	☐

IV. Additional Findings

1. The alternate brand name for the product 2015 is *SurfaceWise*™.

2. The following sentence (guideline 830.1900-Submittal of Samples) "Samples will be sent upon request" has been submitted on a separate e-mail attachment and it should also be added to the Data Matrix, dated 04/23/2018 (see attached separate page, dated 06/25/2018).

Product ingredient source information may be entitled to confidential treatment

3. The data in support of the current registration were generated using the batches of the product manufactured with the end-use product [redacted] as the source for the active ingredient, instead of the manufacturing-use product [redacted] as listed on the proposed Basic CSF. According to the CSFs, the aforementioned two products (see MRID 50576312), are substantially similar. Therefore, any data generated using the end-use product should still support the current application which uses the manufacturing-use product as the source for the active ingredient.

4. The analytical quantification method (Guideline 830.1800-Enforcement analytical method) for the active ingredient is **not validated** in terms of linearity, precision, and accuracy (MRID 50576302).

5. The proposed Basic CSF, dated 04/23/2018, is accepted.

6. The proposed label was screened as it pertains to the product chemistry requirements. The final review of the product label is the purview of the PM team.

Table 1: Accelerated Storage Stability at 54±2 °C (Guideline §830.6320, MRID# 50576311)

Test Substance Identification: Reference Identification:2015 Label Identification: SurfaceWise™2015			
Lot/Batch(s): PR05241701			
Procedure	**Time Interval**		
	Initial	**After 14 days**	**% Difference**
Average % Weight of Quaternary Amines	**0.650**	0.675	**+3.8**

An accelerated storage stability study was conducted on the test substance (Lot No. PR05241701) stored in HDPE (high density polyethylene) containers at 54±2°C for 14 days. The content of the active ingredient is determined initially and after 14 days and the results showed that the product, 2015, is stable at 54±2°C for 2 weeks. There is no significant change in the active ingredient content except for the small weight change(increased). No physical change of the test substance and no significant weight change of the containers are observed during the test period. No corrosion and deterioration of the packaging material are noted.

The average initial content (0.650% w/w) of the active ingredient of the product, 2015, is below the lower certified limit (0.675%). (MRID 50576311). The analytical method used for the quantification of the active ingredient in the product is claimed to be validated, although no validation data is included (MRID 50576311).

V. Conclusion

The Product Science Branch of The Antimicrobials Division finds the proposed Basic CSF, dated 04/23/2018, to be acceptable. Group A guidelines have been met with the exception of guideline 830.1800-Enforcement analytical method (**See IV. Additional Finding #4**). Group B guidelines have been met.

VI. Table A:
Series 830 guidelines – Group A

OCSPP#	Name	Status	MRID
830.1550	Product Identity & Composition	Acceptable	50576301
830.1600	Description of materials	Acceptable	50576301, 50576312
830.1620	Description of production process	Not applicable, non-integrated	N/A
830.1650	Description of formulation process	Acceptable	50576301
830.1670	Discussion of formation of impurities	Acceptable	50576301
830.1700	Preliminary analysis	Not applicable, non-integrated	N/A
830.1750	Certified limits	Acceptable	MRID 50576301, Basic CSF (dated 04/23/2018)
830.1800	Enforcement analytical method	**Requires upgrading**	50576302
830.1900	Submittal of samples	Acceptable-"Samples will be sent upon request" (Addressed on a separate sheet and provided as an e-mail attachment, see attached e-mail, dated	N/A

VII. Table B: Series 830 guidelines – Group B

OCSPP#	Name	Study Findings/Comment	Status	MRID
830.6302	Color	Clear(1-)	Acceptable	50576303 and 50576304
830.6303	Physical state	Liquid	Acceptable	50576304 and 50576304
830.6304	Odor	Odorless	Acceptable	50576304 and 50576304
830.6313	Stability to normal & elevated temperatures, metals & metal ions	The product is not TGAI	Not applicable	N/A
830.6314	Oxidation/Reduction	The product is compatible with all reagents tested (water, carbon dioxide, iron powder, 1% sodium hypochlorite and gasoline).	Acceptable	50576303 and 50576304
830.6315	Flammability	Flash point: > 93.8°C	Not applicable	50576303 and 50576304
830.6316	Explodability	Product does not contain explosive ingredients	Not applicable	50576303
830.6317	Storage stability	The accelerated storage stability study showed that the product was stable at 54±2°C for 14 days.	Acceptable	50576311
830.6319	Miscibility	Product not mixed with organic solvents	Not applicable	50576303
830.6320	Corrosion characteristics	No corrosion of the packaging material was observed during	Acceptable	50576311

OCSPP#	Name	Study Findings/Comment	Status	MRID
		the 14-day storage stability study at 54±2°C.		
830.6321	Dielectric breakdown voltage	Product not used near electrical equipment	Not applicable	50576303
830.7000	pH	5.74 at 25 C (1% w/v aqueous solution)	Acceptable	505763043 and 50576304
830.7050	UV/Visible absorption	Not required for MUP or EP	Not applicable	N/A
830.7100	Viscosity	1.88 cSt at 20 C, 1.29 cSt at 40 C	Acceptable	50576303 and 50576304
830.7200	Melting point	Not required for MUP or EP	Not applicable	N/A
830.7220	Boiling point	Not required for MUP or EP	Not applicable	N/A
830.7300	Density/relative	0.9995=0.9995g/ml=8.3412lb/gal	Acceptable	50576303 and 50576304
830.7370	Dissociation constants in water	Not required for MUP or EP	Not applicable	N/A
830.7520	Particle size	Not required for MUP or EP ("This product is not water insoluble test substance or fibrous test substance".)	Not applicable	50576303
830.7550/ 7560/ 7570	Partition coefficient	Not required for MUP or EP	Not applicable	N/A
830.7840/ 7860	Water solubility	Not required for MUP or EP	Not applicable	N/A
830.7950	Vapor pressure	Not required for MUP or EP	Not applicable	N/A

CONFIDENTIAL ATTACHMENT

Note to PM:

“The average initial content (0.650% w/w) of the active ingredient of the product, 2015, is below the lower certified limit (0.675%)” must be addressed with the Efficacy Team.

Confidential Statement of Formula may be entitled to confidential treatment